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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/730,346

12/08/2003

Edward Russell Cox

P148

1778

27752 7590 04/30/2009
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EXAMINER

MATTISON, LORI K

ART UNIT

PAPER NUMBER

1619

MAIL DATE

DELIVERY MODE

04/30/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/730,346	Applicant(s) COX ET AL.	
	Examiner LORI MATTISON	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/05/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-15 and 26-59 is/are pending in the application.
- 4a) Of the above claim(s) 55-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-15 and 26-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/13/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. All correspondence regarding this application should be directed to Group Art Unit 1619.

Status of Claims

.Applicant's amendments filed 01/05/2009 to claims 1 and 9-15 have been entered. Claims 8 and 17-25 have been cancelled. Claims 1-7, 9-15, and 26-59 remain pending in the current application, of which claims 1-7, 9-15, 26-54 are being considered on their merits. Claims 55-59 remain withdrawn from consideration at this time. References not included with this Office action can be found in a prior action. Any rejections of record not particularly addressed below are withdrawn in light of the claim amendments and applicant's comments.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-7, and 9-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The edible composition, as claimed, has the same characteristics as those found naturally, for example in Montmorillonite clay [see evidentiary reference US Publication No. 2003/0077254 (Ramaekaers, 2003)], which comprises the recited/disclosed amounts of zinc (0.539 mg or 0.0019%), manganese (4.04 mg, or 0.014%), protein (1116 mg or 3.9%), and phosphate (8.62 mg or 0.03%) (page 2, Table 1, paragraph 44) which may be orally administered to animals and is believe by some to compensate for

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elements no longer in foods because of depleted soils (page 2, paragraph 41; page 5, paragraph 77) and therefore does not constitute patentable subject matter. See *American Wood v. Fiber Disintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brodgex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980). It is suggested that claims 1, 2, 5, 11, 14, and 15 be amended by inserting the terminology that would distinguish the claimed edible composition from those that may exist naturally.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4, 5, 29, 31, 35, 36, 39, 42, 46, 47, 50, and 54 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims recite the relative term "at least about" which is indefinite. M.P.E.P. § 2173.05 (b) states, "the court held that claims reciting "at least about" were invalid for indefiniteness where there was close prior art and there was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term "about." *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991)."

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language..

Claims 1, 2, 5, 11, 14, and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by US Publication No. 2003/0077254 (Ramaekaers, 2003).

Ramaekaers discloses the limitations of instant claim 1 by disclosing the components of Montmorillonite clay. The clay comprises the soluble mineral components zinc, manganese, protein, and phosphate (page 2, Table 1, paragraph 44) which may be orally administered to animals (page 5, paragraph 77) and is believe by some to compensate for elements no longer in foods because of depleted soils (page 2, paragraph 41) thereby demonstrating the components are in an amount effective to treat malnutrition.

Ramaekaers discloses the limitations of instant claim 2 by disclosing that zinc comprises 0.0019% weight of montmorillonite clay composition, manganese comprises 0.014% weight of montmorillonite clay composition, protein comprises 3.9% weight of montmorillonite clay composition, and phosphate comprises 0.03% weight of montmorillonite clay composition.

Ramaekaers discloses the limitations of instant claim 5 by disclosing that the zinc, manganese, and phosphate comprise 0.0459% of the composition.

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Ramaekaers discloses the limitations of instant claim 11 by disclosing that montmorillonite clay comprises a mixture of zinc, manganese, copper, and tin (page 2, paragraph 44).

Ramaekaers discloses the limitations of instant claim 14 by disclosing that montmorillonite clay compensates for elements no longer in foods because the depleted soils indicating that the montmorillonite clay is edible and is a food (page 2, paragraph 41).

Ramaekaers discloses the limitations of instant claim 15 by providing the components of Montmorillonite clay (page 2, paragraph 44). Rawhide is not a component.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States .

Claims 1, 11, and 13- 15 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 4,145,447 (Fisher, 1979).

Example 1 of Fisher discloses the limitations of instant claim 1 by disclosing a compact animal food (i.e. edible composition adapted for use by a companion animal) which comprises the soluble minerals, manganese sulfate, zinc sulfate, and copper oxide; a source of protein, Meat meal; and a phosphate component, dicalcium

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phosphate (column 5, lines 15-35). Fisher discloses that that invention is characterized by a chew-resistant, compacted, self-contained unit which contains the pet meal (column 2, lines 50-60), thus the components of the compact animal food are in an amount sufficient to act as an oral medicament against malnutrition and starvation.

Example 1 of Fisher discloses the limitations of instant claim 11 by disclosing a compact animal food which comprises three soluble minerals, manganese, zinc and copper (column 5, lines 15-35).

Example 1 of Fisher discloses the limitations of instant claim 13 by disclosing a compact animal food has high chew life and unit integrity when eaten by dogs, thus the compact animal food product is a chew (column 5, lines 10-20).

Example 1 of Fisher discloses the limitations of instant claim 14 by disclosing that the composition of Example 1 is a compact animal food (column 5, lines 5-10).

Example 1 of Fisher meets the limitations of instant claim 15 by disclosing the list of ingredients. Rawhide and/or collagen is not present on the list of component ingredients (column 5, lines 5- 68).

Claims 1, 2, 5, 14, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,069,903 (Stitt, 1991).

Example VI (column 14, lines 45-end; column 13, lines 1-40) of Stitt discloses the limitations of instant claim 1 by disclosing a fortified flax seed diet which improves the growth rate of chickens (i.e. an edible composition adapted for a companion animal). The fortified tied comprises dicalcium phosphate, soy meal (protein source), zinc, and a

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vitamin premix which comprises manganese (column 13, lines 1-15). Chickens fed the fortified flax seed diet demonstrated faster growth than those not fed the fortified diets (column 13, lines 25-40).

Example VI (column 14, lines 45-end; column 13, lines 1-40) of Stitt discloses the limitations of instant claim 2 by disclosing that the fortified diet comprised zinc in an amount of 0.2% by weight and manganese in an amount of 0.00005% which is about 0.0001%

Example VI (column 14, lines 45-end; column 13, lines 1-40) of Stitt discloses the limitations of instant claim 5 by disclosing that the fortified diet comprised zinc in an amount of 0.2% by weight and manganese in an amount of 0.00005% (which is about 0.0001%), for a combined percentage of mineral component equal to 0.20005%.

Example VI (column 14, lines 45-end; column 13, lines 1-40) of Stitt discloses the limitations of instant claim 14 by disclosing that the composition of Example VI is a flax seed diet, i.e. food (column 5, lines 5-10).

Example VI (column 14, lines 45-end; column 13, lines 1-40) of Stitt meets the limitations of instant claim 15 by disclosing the list of ingredients. Rawhide and/or collagen is not present on the list of component ingredients (column 14, lines 45-end; column 13, lines 1-40).

Applicant's arguments regarding the withdrawn art rejections of record have been considered to the extent they read on the new grounds of rejection of the amended claims.

Applicant alleges that the prior art does not teach a soluble mineral component, a phosphate component, and a protein source as required by the amended claim (Reply, pages 14 and 15). This issue has been addressed by the inclusion of the new Stitt and Fisher references which disclose soluble mineral component, a phosphate component, and a protein source which act as oral medicaments against malnutrition and to aid in growth.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 9, 10, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,350,485 (Brunner, 2002).

Brunner meets the limitations of instant claim 1 by teaching a typical dry cat food composition (i.e. an edible composition adapted for use by a companion animal). The formulation comprises 0-30% animal by-product meal (protein source), 0-25% fresh animal tissue (protein source), 0-25% soybean meal (protein source), 0-20% seafood-

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based meal (protein source), and 0-25% fresh fish tissue (protein source). Brunner goes on to teach that protein content of commercially available cat food compositions for adult non-breeding cats is about 30% by weight dry matter basis to insure that the food meets the nutritional requirements for any cat (column 3, lines 35-45). Brunner goes on to teach that vitamins and minerals are added to the typical animal food according to known American Association of Feed Control Officials (AAFCO) cat nutrient profiles which comprising zinc oxide and copper sulfate (i.e. an effective amount for use as an oral medicament against malnutrition) (column 3, lines 45-end) . The slurry for the typical animal food also comprises a phosphate component, tetrasodium pyrophosphate (column 3, lines 40-60) which is used as a palatability enhancer (column 3, lines 65-end and comprises from about 0.1-1.0% by weight of the finished pet food (i.e. an effective amount for use as an oral medicament against malnutrition). Brunner teaches the limitation by instant claim 9 by teaching that the phosphate component is tetrasodium pyrophosphate (column 3, lines 40-60). Brunner teaches the limitations of instant claim 10 by teaching the polyphosphate, tetrasodium pyrophosphate (column 3, lines 40-60) for inclusion in the cat food. Brunner teaches the limitations instant claim 14 by teaching a typical dry cat food composition (column 3, lines 40-end) which is a companion animal food. Brunner teaches the limitations of instant claim 15 by teaching a typical dry cat food composition (column 3, lines 40-end) which is free of rawhide.

Brunner does not specifically teach the amount protein present in the typical cat food formulation.

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It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have added protein from one or more of the five sources taught by Brunner to Brunner's typical cat food formulation in an amount of 30% by weight of the composition because Brunner teaches that protein in an amount of 30% is added to commercial cat formulations so that they meet the nutritional requirements for any cat.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brunner as applied to claims 1, 9, 10, 14, and 15 above, and further in view of US Patent No. 4,039,687 (Weyn, 1977) and US Publication No. 2003/0175387 (English, 2003).

Brunner does not teach that his cat food composition is an animal biscuit as set forth by instant claim 12.

Weyn teaches that dry meal type ration cat food may be compressed into biscuit form (column 1, lines 10-30).

English teaches biscuits are fed to animals between meals or as a supplement to meals (page 1, paragraph 2).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have modified the food composition taught by Brunner to form a cat biscuit as taught by Weyn in order to provide a food product for cats which can be served between meals or as a meal supplement as taught by English.

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Claims 2, 5, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brunner as applied to claims 1, 9, 10, 14, and 15 above, and further in view of the Merck Veterinary Manual 8th Edition as copyrighted in 1998.

The limitations of instant claims 1, 9, 10, 14, and 15 are addressed above. Brunner invites routine optimization of the "typical cat food" formulation by teaching that vitamins and minerals are added to the typical cat food according to known AAFCO cat food nutrient profiles which include zinc oxide and copper sulfate (column 3, lines 55-65). Brunner provides extends an additional invitation to optimize the composition by teaching, "the pet food compositions described herein are not intended to be limited to specific listings of ingredients... In addition to the proteinaceous and farinaceous material, the pet food composition generally may include vitamins..." (column 2, lines 60-end).

Brunner does not teach the amount of zinc and copper ions used in the "typical pet food composition" as set forth by instant claim 2.

Brunner does not teach the percentage of the mineral component by weight of the composition in the typical pet food composition as set forth by instant claim 5.

Brunner does not teach that the typical cat food composition comprises three or more metals comprising zinc, copper, tin, and manganese as set forth by instant claim 11.

The Merck Veterinary Manual (from hereinafter Merck) teaches the AAFCO Nutrient requirement for cats (page 1627). Cat foods require 0.005% copper by weight percent of the composition (page 1627). Cat foods require a minimum of 0.0075%

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(which is about 0.001%) and a maximum of 0.2% zinc by weight percent of the composition (page 1627). Merck also teaches that cat foods require manganese, in addition to copper and zinc (page 1627).

With regard to instant claim 2, it would therefore have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have optimized the typical cat food composition taught by Brunner to include about 0.001% zinc ion and 0.005% copper ion because Brunner teaches that vitamins and minerals of Brunner's composition should be added to the typical cat food composition in accordance to AAFCO guidelines and the AAFCO guidelines require about 0.001% of zinc and 0.005% of copper ion to be present.

With regard to instant claim 5, it would therefore have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to optimized the mineral component of Brunner's typical cat food composition to include 0.2% minerals because Brunner teaches optimizing the typical cat food to the requirements set forth by the AAFCO and the AAFCO teaches that cat food formulations are required to comprise a combination of zinc and copper in an amount between 0.0125%-0.2005% by weight .

With regard to instant claim 11, it would therefore have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have added copper, zinc, and manganese to the Brunner's typical cat food composition because Brunner teaches that minerals are to be added in accordance to the AAFCO guidelines

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and the AAFCO guidelines require copper, zinc, and manganese to be present in cat food.

Claims 3, 4, 6, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brunner and the Merck Veterinary Manual 8th Edition as applied to claims 1, 2, 5, 9, 10, 11, 14, and 15 above, and further in view of US Patent No. 5,405,836 (Richar, 1995).

Brunner teaches a typical cat food composition comprising zinc oxide and copper sulfate (column 3, lines 55-65). Brunner teaches that minerals are to be added to the typical cat food composition in accordance to AAFCO guidelines (column 3, lines 50-60).

Merck teaches the limitations of instant claim 7 by teaching that the AAFCO Nutrient requirement for cats (page 1627) require 0.005% copper by weight percent of the composition (page 1627) to be present in cat food. The guidelines also require a minimum of 0.0075% (which is about 0.001%) and a maximum of 0.2% zinc by weight percent of the composition (page 1627).

Neither Brunner or Merck teach a cat food composition comprising a zinc salt from the group consisting of zinc sulfate, zinc gluconate, zinc chloride, zinc citrate, zinc lactate, zinc malate or mixtures thereof as set forth by instant claim 6.

Richar teaches that zinc sulfate, zinc gluconate, and zinc chloride topically applied to dry pet food, in some cases as a coating, to control breath odor of cats (column 6, lines 10-35; column 6, lines 25-30). Richar goes on to teach the limitations

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of instant claim 7 by teaching that the water soluble zinc salts which are topically applied comprise from about 2 mg to about 6 mg of zinc ion per 10 gram of breath freshening pet food (i.e. 0.02-0.06% by weight of the composition; column 5, lines 20-30)

With regard to instant claim 6, it would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to modified Brunner's typical cat food composition by topically adding zinc sulfate, zinc chloride, or zinc gluconate to Brunner's typical cat food composition in order to control the breath odor of cats through topical application of the zinc sulfate, zinc chloride, or zinc gluconate to dry pet food as taught by Richar.

With regard to instant claim 7, It would therefore have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have optimized the amount of zinc ion to be about 0.001% to about 1% zinc ion by weight of the composition because Richar teaches use of zinc ion topically applied to dry pet food to freshen breath in an amount of 0.02% to about 0.06% by weight of the composition, being in accordance with Brunner's requirement that minerals added to the composition are in accordance to AAFCO Nutrient requirement for cats. It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have optimized the Brunner's composition to include 0.005%-0.1% copper ion because Brunner teaches optimizing the typical cat food to the requirements set forth by the AAFCO and the AAFCO teaches that cat food formulations are required to comprise 0.005% copper ion.

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With regard to instant claim 3, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have optimized Brunner's typical cat food composition by topically adding zinc sulfate, zinc chloride, or zinc gluconate, i.e. a portion of the mineral component, to Brunner's typical cat food composition in order to control the breath odor of cats through topical application of the zinc sulfate, zinc chloride, or zinc gluconate to dry pet food as taught by Richar.

With regard to instant claim 4, The selection of at least about 50% of the mineral compound on coated on the surface of the animal food product would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that zinc which may be coated on the outside of the food product as taught by Richar may be present in cat food in an amount 40 fold higher than that of copper which is not taught for inclusion in the coating and be within the AAFCO nutritional guidelines as taught by Merck . A holding of obviousness over the cited claims is therefore clearly required.

Instant claim 26 remains rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication No. 2002/0119224 (Axelrod, 2002) and U.S. Patent 5,296,209 (Simone, 1994)

Axelrod teaches an animal chew toy (paragraph 1). One of objectives of the chew toy is to enrich the animals diet with vitamins/minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6). Axelrod meets the limitations of instant claim 26 by specifically teaching preferential inclusion manganese, and copper in the composition and discloses potential inclusion of

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tin (paragraph 16). Axelrod goes on to further teach that these minerals (*i.e.* the additives) are a part of a water solution containing the vitamins/minerals and/or herbs employed (paragraph 18). These are incorporated into a soaking solution and allowed to coat and or penetrate the molded chew toy, thus teaching the limitation that a least a portion of the mineral component is coated on the surface of the edible composition (paragraph 18). Axelrod also recognizes a need for inclusion of vitamin and mineral supplements (such as glucosamine) to ensure proper health and prevent malnutrition (paragraph 4). Axelrod teaches that phosphorus is present (paragraph 16).

However, Axelrod does not teach inclusion of a phosphate component in or on the chew for use as an oral medicament as set forth by instant claim 26.

Simone teaches a chew that contains an inorganic pyrophosphate incorporated into a chew (Col. 4 lines 6-10). Simone teaches plaque is generally recognized as the main culprit of poor oral health. Bacteria that produce the acid cause redness and swelling (gingivitis). If the bacteria spread they cause malodor, periodontal disease, gingival pockets and bone loss (column 1, lines 10-25). Simone further teaches that tartar contains unmineralized plaque that can cause constant irritation and other problems once calculus (*i.e.* tartar) is formed below the gum line (column 1, lines 10-45). Simone teaches that inorganic pyrophosphate salts serve as a tartar control additives (Col. 4 lines 6-10). Table 1 of Simone also demonstrates that pyrophosphate salts reduce plaque when placed on chew products (column 9, lines 25-end).

Therefore, it would be *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made to improve the chew toy of Axelrod by adding

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pyrophosphate salts to the chew toy taught Axelrod because Axelrod recognizes a need for inclusion of vitamins, minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained to ensure proper health and Simone teaches that inclusion of pyrophosphate salts in chews prevents tartar and reduces plaque both of which cause poor oral health, periodontal disease, constant irritation and other problems.

In regard to instant claim 26, applicant alleges that there would be little expectation of success in arriving at the claimed invention because Axelrod makes no mention of use of the pet food for reducing tartar and Simone fails to disclose one or more minerals selected from the group consisting of zinc, manganese, tin and copper for use in Simone's chew (Reply, page 18, paragraph 2). The examiner disagrees. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Axelrod clearly states that one of objectives of the chew toy is to enrich the animals diet with vitamins/minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6). Simone clearly teaches that bacteria and tartar negatively impact an animal's comprehensive needs by disclosing that bacteria (i.e. plaque) that produce the acid cause redness, swelling (gingivitis), malodor, periodontal disease, gingival pockets and bone loss (column 1, lines 10-25). Simone

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further teaches that tartar contains unmineralized plaque that can cause constant irritation and other problems once calculus (i.e. tartar) is formed below the gum line (column 1, lines 10-45). Therefore, it would be obvious to add the pyrophosphate salts taught by Simone to Axelrod's chew in order to maintain the animal's comprehensive health by reducing plaque/bacteria and tartar, thereby reducing the maladies in which they cause, especially in light of Axelrod's invitation to optimize the mineral component chew to meet the animals comprehensive needs (page 1, paragraph 6). With regard to Applicant's allegation that one of ordinary skill in the art would have no reasonable expectation of success in combining the references to arrive at the claimed invention (Reply, page 18, paragraph 2), M.P.E.P. § 2143 states, "Obviousness does not require absolute predictability of success." *Id.* at 903, 7 USPQ2d at 1681. Lastly, in response to applicant's argument regarding inclusion of an effective amount of mineral component comprising one or more minerals selected from the group of zinc, manganese, tin, copper, and more minerals wherein the amount is an effective amount for use as an oral medicament and further amount of phosphate component wherein the further amount is an effect amount for use as an oral medicament, a recitation of the intended use (i.e. an effective amount for an oral medicament) of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

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Instant claims 27 and 28 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Axelrod and Simone, as applied in instant claim 26, in further view of U.S. Patent No. 6,060,100 (Koller, 2000).

The limitations of instant claim 26 are addressed above.

Axelrod meets the limitations of instant claim 28 by specifically teaching preferential inclusion of zinc, manganese, and copper in the composition and discloses potential inclusion of tin (paragraph 16). Axelrod meets the limitations of instant claim 28 by teaching that

Axelrod teaches that collagen may be present with *either* casein, starch, vegetable matter, rawhide, peanut bits/flour, animal meal and/or any other thermoplastic resin (paragraph 8; italics by examiner for emphasis). Axelrod teaches inclusion of rawhide in a chew (paragraph 29) and chews that contain no rawhide (paragraph 28). Axelrod also recognizes a need for inclusion of vitamin and minerals ensure proper health and prevent malnutrition (paragraph 4).

However, Axelrod does not provide a rationale as to why one chew (rawhide containing versus rawhide-free) would be preferable over the other.

Koller teaches that "rawhide is particularly bad for a dog's health as it is not digestible" (Col.1, lines 37-38).

Simone additionally teaches that rawhide dog chews are expensive and that the indigestible leather fragments swallowed by the dogs frequently cause severe gastrointestinal blockage or diarrhea (Col. 1, lines 54-57).

Therefore, it would be *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made to make the rawhide-free chew as taught by Axelrod . One would have been motivated to do so because Axelrod expresses a desire to ensure the proper health of an animal and Koller and Simone art teaches that rawhide is bad for a dog's health and is expensive.

Applicant alleges that the combination of Axelrod, Simone, and Koller fail to provide one of ordinary skill in the art with a reasonable expectation of success in arriving at the current claims (Reply, page 19, last paragraph) because Koller fails to disclose the use of or the desire to use a mineral component and also fails to disclose a use of or desire to use such minerals in combination with a phosphate component. The examiner disagrees. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, the Koller reference is provided to demonstrate that the skilled artisan, at the time the invention was made, recognized inclusion of rawhide in chews was detrimental to the animal's health, thus providing motivation to make a rawhide free chew. With regard to Applicant's allegation that one of ordinary skill in the art would have no reasonable expectation of success in combining the references to arrive at the claimed invention (Reply, page 19, last paragraph), M.P.E.P. § 2143 states, "Obviousness does not require absolute predictability of success." *Id.* at 903, 7 USPQ2d at 1681.

Instant claims 29-31 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Axelrod, Simone, and Koller, as applied in instant claims 26-28 above, in further view of the Merck Veterinary Manual 8th Edition as copyrighted in 1998.

The limitations of instant claims 26-28 are addressed above.

Axelrod teaches inclusion of zinc, manganese, and copper in the composition and discloses potential inclusion of tin (paragraph 16). Axelrod also teaches that one of its objectives is to enrich the animal's diet with vitamins/minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6). Axelrod also teaches that one of the deficiencies of natural, organic, and vegetarian diets developed by owners is that many of the published recipes have not been properly balanced using nutrient averages as taught by The Merck Veterinary Manual 8th Edition (paragraph 4). Axelrod provides an invitation to optimize the amount of minerals present in the composition by teaching that, "the chew toy can therefore be modified to reflect a higher or lower concentration of a given mineral according to nutritional requirements (page 2, paragraph 16).

Simone teaches the limitations of instant claim 30 by teaching that the inorganic pyrophosphate is incorporated (i.e. integrated) into a chew in order to inhibit tartar formation on the animal's teeth (Col. 4 lines 6-15).

Neither Axelrod, Simone, and Koller teach any specific percentages for the minerals that are to be included in the taught chew, as set forth by instant claim 29.

Axelrod does not teach integration of the phosphate component in the chew as set forth by instant claim 30.

Neither Axelrod, Simone, and Koller teach that the composition comprises at least about 0.02% mineral component, as set forth by instant claim 31.

The Merck Veterinary Manual 8th Edition teaches that the minimum nutrient requirement for dogs for zinc, manganese, and copper (all of which are included in the composition taught by Axelrod) is 0.012%, 0.0005%, and 0.00073% respectively by weight (page 1626). The sum of these percentages is 0.013%, which is at least about 0.01% (page 1626). The Merck Veterinary Manual 8th Edition also teaches that AAFCO Nutrient Requirements for dogs require manganese in an amount that is 0.0005% by weight (page 1626). Merck teaches that the AAFCO guidelines for the amount of zinc present in the composition is optimizable with the amount of zinc required ranging from is 0.012% - 0.1 % by weight (page 1626). Merck also teaches that the AAFCO guidelines for the amount of copper present in the composition is optimizable with the amount of copper required ranging from 0.00073% -0.025% by weight of the composition (page 1626). Therefore the amount of the recited minerals can range from 0.01323-0.1255% (page 1626).

With regard to instant claim 29, it would have been *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made to include at least about 0.01% minerals in the composition taught by Axelrod. One would have been motivated to do so because Axelrod art teaches enriching the chew with vitamins, minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are

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maintained (paragraph 6) and the proper minimum amount of zinc, manganese, and copper required to meet the nutrient requirement for a dog is within the disclosed range. Furthermore, recitation of a mineral component greater than 0.01% is simply optimization of a result effective variable within a range that was previously taught by the Merck.

With regard to instant claim 30, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have incorporated pyrophosphate into the composition chew taught by Axelrod because Simone teaches that pyrophosphates are incorporated into chew to inhibit tartar formation.

With regard to instant claim 31, it would have been *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made to optimize the amount of minerals to comprise about 0.02% of Axelrod's chew because Axelrod provides an invitation to optimize the composition according to nutritional requirement and Merck teaches that AAFCO nutrient requirements require copper, zinc, and manganese to be present in compositions in an amount from 0.01323-0.1255%. Recitation of a mineral component, "of at least about 0.02%" is simply optimization of a result effective variable within a range that was previously taught by the prior art.

Applicant alleges that the combination of Axelrod, Simone, Koller, and Merck fails to provide one of ordinary skill in the art with the expectation of success in arriving at the current claims because Merck fails to disclose use of or the desire to use a mineral

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component comprising one or more minerals selected from zinc, manganese, tin, and copper in combination with a phosphate component (Reply, 20, paragraph 2). The examiner disagrees. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, Axelrod teaches inclusion of zinc, manganese, and copper in the composition and discloses potential inclusion of tin (Axelrod, paragraph 16). While Axelrod does not teach the specific percentages of the mineral components does discuss the nutritional requirements for dogs in relation to the amounts of minerals and provides an invitation to optimize the amount of minerals in the composition according to nutritional requirements (page 2, paragraph 16). Merck is provided to teach the AAFCO's nutritional requirements for dog's (page 1626) per kg of diet. With regard to Applicant's allegation that one of ordinary skill in the art would have no reasonable expectation of success in combining the references to arrive at the claimed invention (Reply, page 19, last paragraph), M.P.E.P. § 2143 states, "Obviousness does not require absolute predictability of success." *Id.* at 903, 7 USPQ2d at 1681.

Instant claims 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Axelrod, Simone, Koller, and the Merck Veterinary Manual 8th Edition, as applied

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in instant claims 26-31 above, in further view of U.S. Patent No. 6,277,435 (Lacombe, 2001) and U.S. Patent No. 3,422,182, (Knapp, 1962).

The limitations of instant claims 26-31 are addressed supra.

Axelrod teaches that the minerals are incorporated in a soaking solution and that the minerals can penetrate the chew (paragraph 18), demonstrating that these are water-soluble mineral salts. Axelrod specifically prefers inclusion of zinc, manganese, and copper in the composition and discloses potential inclusion of tin (paragraph 16).

Simone teaches the limitations of instant claims 33, 34, and 35 by teaching that the inorganic pyrophosphate (i.e. polyphosphate) is incorporated (i.e. integrated) into a chew (Col. 4 lines 6-10). Concentrations of pyrophosphate that are suitable are taught to be 0.5 to about 15% dry weight of the chew product (Col. 4, lines 15-19).

Neither Axelrod, Simone, Koller, and Merck teach specific water soluble mineral salts as set forth by instant claim 32.

Axelrod does not teach that at least a portion of the phosphate component is a polyphosphate as set forth by instant claim 33.

Axelrod does not teach that at least a portion of phosphate component is a pyrophosphate as set forth by instant claim 34.

Axelrod does not teach that at least about 0.05% of the phosphate component, by weight of the composition as set forth by instant claim 35.

Axelrod does not teach that at least about 0.5% of the phosphate component, by weight of the composition as set forth by instant claim 36.

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Lacombe recites a pet food which can be served daily, with noticeable improvement in the animal's health" (Col.3, lines 1-3). This pet food contains the soluble mineral components copper sulfate, and manganese sulfate (Col.4, lines 3-10).

Knapp teaches administration of zinc in an animal's drinking water or food (Col 2. lines 41-50) to treat mange. Zinc sulfate and zinc chloride are disclosed as being water soluble zinc salts (Col. 2, lines 60-65) which may be administered.

With regard to instant claim 32, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to include copper sulfate, manganese sulfate, and/or zinc sulfate and zinc chloride in Axelrod's chew because Axelrod expresses a desire to enrich the chew with minerals, such as manganese, zinc, and copper, to ensure that the animal's comprehensive and proper nutritional needs are maintained and copper sulfate, manganese sulfate, and/or zinc sulfate and zinc chloride are water soluble salts of these desired minerals taught to be able to be ingested by dogs as taught by Lacombe and Knapp.

With regard to instant claim 33, would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to improve the Axelrod's chew toy by adding pyrophosphate salts (i.e. polyphosphate) to the chew toy because Axelrod recognizes a need for inclusion of vitamins, minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained to ensure proper health and Simone teaches that inclusion of pyrophosphate salts in chews prevents tartar and reduces plaque both of which cause poor oral health, periodontal disease, constant irritation and other problems.

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With regard to instant claim 34, would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to improve the Axelrod's chew toy by adding pyrophosphate salts to the chew toy because Axelrod recognizes a need for inclusion of minerals to ensure that the animal's comprehensive and proper nutritional needs are maintained to ensure proper health and Simone teaches that inclusion of pyrophosphate salts in chews prevents tartar and reduces plaque both of which cause poor oral health, periodontal disease, constant irritation and other problems.

With regard to the limitations of instant claim 35, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have added at least 0.05% of a phosphate component to Axelrod's chew toy because Axelrod recognizes a need for inclusion of minerals to ensure that the animal's comprehensive and proper nutritional needs are maintained to ensure proper health and Simone teaches that inclusion of pyrophosphate salts in an amount of 0.5 % to about 15% dry weight in chews prevents tartar and reduces plaque both of which cause poor oral health, periodontal disease, constant irritation and other problems. Recitation of a phosphate component, "at least about 0.05%" is simply optimization of a result effective variable within a range that was previously taught by the prior art.

With regard to the limitations of instant claim 36, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have added at least 0.5% of a phosphate component to Axelrod's chew toy because Axelrod recognizes a need for inclusion of minerals to ensure that the animal's

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comprehensive and proper nutritional needs are maintained to ensure proper health and Simone teaches that inclusion of pyrophosphate salts in an amount of 0.5 % to about 15% dry weight in chews prevents tartar and reduces plaque both of which cause poor oral health, periodontal disease, constant irritation and other problems. Recitation of a phosphate component, "at least about 0.5%" is simply optimization of a result effective variable within a range that was previously taught by the prior art.

Applicant alleges that combination of Axelrod, Simone, Koller, Merck, Lacombe, and Knapp fail to provide one of ordinary skill with a reasonable expectation of success in arriving at the current claims (Reply, page 20, paragraph 4; page 5, paragraph 1). The examiner disagrees. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Furthermore, with regard to the subject matter of the selected references, M.P.E.P. § 2123 discloses, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). Lastly, with regard to Applicant's allegation that one of ordinary skill in the art would have no reasonable expectation of success in combining the references to arrive

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at the claimed invention, M.P.E.P. § 2143 states, "Obviousness does not require absolute predictability of success." Id. at 903, 7 USPQ2d at 1681.

Instant claim 37 remains rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication No. 2002/0119224 (Axelrod, 2002) and U.S. Patent 5,011,679 (Spanier, 1991).

Axelrod teaches an animal chew toy (paragraph 1). One of objectives of the chew toy is to enrich the animal's diet with minerals to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6). Axelrod also recognizes a need for inclusion of vitamin and mineral supplements to ensure proper health and prevent malnutrition (paragraph 4). Axelrod teaches the limitations of instant claim 37 by specifically teaching preferential inclusion of zinc, manganese, and copper in the composition and discloses potential inclusion of tin (paragraph 16). Axelrod goes on to further teach that these minerals are incorporated into a soaking solution and allowed to coat and or penetrate the molded chew toy, thus teaching the limitation that at least a portion of the mineral component is coated on the surface of the edible composition (paragraph 18). Axelrod teaches that phosphorus is present (paragraph 16).

Axelrod does not teach inclusion of a phosphate component on the surface of the chew as set forth by instant claim 37.

Spanier teaches a rawhide chew containing a pyrophosphate coating (Abstract). The object of the chew is to prevent tartar accumulation on dog's teeth by the chewing

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and eating of raw hide having a coating containing pyrophosphate (Col. 8, lines 1-5). Spanier teaches that the inorganic pyrophosphates used in the invention are anti-tartar, anti-plaque or anticalculus agents (column 9, lines 55-60) and have an anti-cariogenic effect (Col.8, lines 34-41). It is preferred that the pyrophosphates are water soluble (Col. 11, lines 37-38). Spanier recognizes that tartar is detrimental to animal health by teaching that calculus deposits (tartar) are constant sources of irritation of the gingiva and thereby and thereby are a contributing factor to gingivitis and other diseases of the supporting structures of the teeth, irritation decreasing the resistance of tissues to endogenous and exogenous organisms (column 1, lines 20-35). Spanier teaches the limitations of instant claim 37 by teaching that the coating slurry (which contains the pyrophosphate) may be applied to the rawhide chew by any suitable means such as spraying or soaking (Col. 14, lines 1-3).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have added the water-soluble pyrophosphate taught by Spanier in the soaking solution taught by the Axelrod to coat and penetrate Axelrod's animal chew toy because Axelrod teaches inclusion of minerals to meet the comprehensive needs of the animal and ensure proper health and Spanier teaches that pyrophosphate coatings on chews prevent tartar and cavities.

Applicant alleges that the combination of Axelrod and Spanier fail to provide one of ordinary skill in the art with a reasonable expectation of success in arriving at the claimed invention (Reply, page 22, paragraph 1). The examiner disagrees. In response

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to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Furthermore, with regard to the subject matter of the selected references, M.P.E.P. § 2123 discloses, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned.

They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). Lastly, with regard to Applicant's allegation that one of ordinary skill in the art would have no reasonable expectation of success in combining the references to arrive at the claimed invention, M.P.E.P. § 2143 states, "Obviousness does not require absolute predictability of success." *Id.* at 903, 7 USPQ2d at 1681.

Instant claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Axelrod and Spanier *et al*, as applied to instant claim 37 above, in further view of U.S. Patent No. 6,060,100 (hereinafter '100) by Koller.

The limitations of instant claim 37 are addressed above.

Axelrod teaches that collagen may be present with *either* casein, starch, vegetable matter, rawhide, peanut bits/flour, animal meal and/or any other thermoplastic resin (paragraph 8; italics by examiner for emphasis). Axelrod teaches

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inclusion of rawhide in a chew (paragraph 29) and chews that contain no rawhide (paragraph 28). Axelrod also recognizes a need for inclusion of vitamin and mineral supplements to ensure proper health and prevent malnutrition (paragraph 4).

However, Axelrod does not provide a rationale as to why one chew (rawhide containing versus rawhide-free) would be preferable over the other.

Koller teaches that “rawhide is particularly bad for a dog’s health as it is not digestible” (Col.1, lines 37-38).

Therefore, it would be *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made to make the rawhide-free chew as taught by Axelrod prior art. One would have been motivated to do so because Axelrod expresses a desire to ensure the proper health of an animal and Koller teaches that rawhide is bad for a dog’s health.

Applicant alleges that combination of Axelrod, Spanier, and Koller fail to provide one of ordinary skill with a reasonable expectation of success in arriving at the current claims (Reply, page 22, paragraph 1). The examiner disagrees. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Furthermore, with regard to the subject matter of the selected references, M.P.E.P. § 2123 discloses, “The use of patents as references is not limited to what the patentees

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describe as their own inventions or to the problems with which they are concerned.

They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). Lastly, with regard to Applicant's allegation that one of ordinary skill in the art would have no reasonable expectation of success in combining the references to arrive at the claimed invention, M.P.E.P. § 2143 states, "Obviousness does not require absolute predictability of success." *Id.* at 903, 7 USPQ2d at 1681.

Instant claims 39, 40, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Axelrod, Spanier, and Koller, as applied to instant claims 37 and 38 above, in further view of *The Merck Veterinary Manual 8th Edition* as copyrighted in 1998.

The limitations of instant claims 37 and 38 are addressed supra.

Axelrod specifically prefers inclusion of zinc, manganese, and copper in the composition and discloses potential inclusion of tin (paragraph 16). Axelrod prior art also teaches that one of its objectives is to enrich the animal's diet with vitamins/minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6). Axelrod also teaches that one of the deficiencies of natural, organic, and vegetarian diets developed by owners is that many of the published recipes have not been properly balanced using nutrient averages as taught in *The Merck Veterinary Manual 8th Edition* (paragraph 4). Axelrod teaches the

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limitations of instant claims 40 and 41 by teaching that the additives (i.e. minerals) that are incorporated into a soaking solution and are allowed to coat and/or penetrate the chew (paragraph 18)

Axelrod does not teach the chew comprising at least about 0.01% of the mineral component as set forth by instant claim 39.

Axelrod does not teach the chew comprising at least about 0.02% of the mineral component as set forth by instant claim 42.

The Merck Veterinary Manual 8th Edition (Merck) teaches that the minimum nutrient requirement for dogs for zinc, manganese, and copper (all of which are included in the composition taught by Axelrod) is 0.012%, 0.0005%, and 0.00073% respectively by weight (page 1626). The sum of these percentages is 0.013%, which is at least about 0.01% and teaches the limitations of instant claim 39. With regard to instant claim 42, Merck teaches that the minimum amount of manganese required in dog food is 5 mg/kg, (or 0.0005% by weight). The minimum amount copper required in dog food is 7.3 mg/kg, (or 0.00073% by weight) while the maximum amount of copper permitted is 250 mg/kg (0.025% by weight). The minimum amount of zinc required is 0.012%. The maximum amount of zinc required is 0.1 % (page 1626). Therefore the amount of the recited minerals can range from 0.01323-0.1255% (page 1626),

With regard to instant claim 39, it would have been *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made to include at least about 0.01% minerals in the composition taught by Axelrod because Axelrod teaches enriching the chew with vitamins, minerals and herbs to ensure that the animal's

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comprehensive and proper nutritional needs are maintained (paragraph 6) and the proper minimum amount of zinc, manganese, and copper required to meet the nutrient requirement for a dog is 0.013%. The recitation of a mineral component greater than 0.01% is simply optimization of a result effective variable within a range that was previously taught by the prior art.

With regard to instant claim 42, it would have been *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made to include at least about 0.02% minerals in the composition taught by Axelrod because Axelrod teaches enriching the chew with vitamins, minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6) and the proper amount of zinc, manganese, and copper required to meet the nutrient requirement for a dog ranges from 0.01323-0.1255%. The recitation of a mineral component greater than 0.02% is simply optimization of a result effective variable within a range that was previously taught by the prior art.

Applicant alleges that combination of Axelrod, Spanier, Koller, and Merck fail to provide one of ordinary skill with a reasonable expectation of success in arriving at the current claims (Reply, page 23, last paragraph). The examiner disagrees. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

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Furthermore, with regard to the subject matter of the selected references, M.P.E.P. § 2123 discloses, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). Lastly, with regard to Applicant's allegation that one of ordinary skill in the art would have no reasonable expectation of success in combining the references to arrive at the claimed invention, M.P.E.P. § 2143 states, "Obviousness does not require absolute predictability of success." *Id.* at 903, 7 USPQ2d at 1681.

Instant claims 43-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Axelrod, Spanier, Koller, and *The Merck Veterinary Manual 8th Edition* as copyrighted in 1998, as applied to instant claims 37-42 above, in further view of U.S. Patent No. 6,277,435 (hereinafter '435) by Lacombe *et al.* and U.S. Patent No. 3,422,182, (hereinafter '182) by Knapp *et al.*

Axelrod does not disclose specific water soluble mineral salts to include in the pet chew as set forth by instant claim 43.

Lacombe recites a pet food which can be served daily, with noticeable improvement in the animal's health" (Col.3, lines 1-3). This pet food contains the soluble mineral components copper sulfate, and manganese sulfate (Col.4, lines 3-10).

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Knapp teaches administration of zinc in the animal's drinking water or food (Col. 2, lines 41-50) to treat mange. Zinc sulfate and zinc chloride are disclosed as being water soluble zinc salts (Col. 2, lines 60-65) which can be administered.

Spanier teaches the limitations of instant claims 44, 45, 46, and 47 by teaching a rawhide chew containing a pyrophosphate coating (Abstract). The examiner notes that pyrophosphate is a polyphosphate. Spanier goes on to teach that the pyrophosphates are used in a sufficient amount to deliver (preferably) from 0.4 to 0.5 weight percent (based on the total composition) of pyrophosphate (Col. 12, lines 40-45).

With regard to instant claim 43, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have added copper sulfate, manganese sulfate, and/or zinc sulfate and zinc chloride to the chew taught by Axelrod. One would have been motivated to do so because Axelrod expresses a desire to enrich the chew with vitamins, minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6). Manganese, zinc, and copper are taught to be included among minerals to be included in Axelrod's chew and may be added to the soaking solution. Copper sulfate, manganese sulfate, and/or zinc sulfate and zinc chloride are water soluble salts of these desired minerals, and are taught to be present in other pet foods (or as supplements that may be added to the pet food) by Lacombe and Knapp prior art.

With regard to instant claim 44, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have added a polyphosphate component to the chew taught by Axelrod because Axelrod teaches

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inclusion of minerals to meet the comprehensive needs of the animal and ensure proper health and Spanier teaches that pyrophosphate coatings, i.e. polyphosphate, on chews prevent tartar and cavities.

With regard to instant claim 45, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have added a pyrophosphate component to the chew taught by Axelrod because Axelrod teaches inclusion of minerals to meet the comprehensive needs of the animal and ensure proper health and Spanier teaches that pyrophosphate coatings on chews prevent tartar and cavities.

With regard to instant claim 46, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have included at least about 0.05% of phosphate by weight of the composition because Axelrod teaches inclusion of minerals to meet the comprehensive needs of the animal and ensure proper health and Spanier teaches that pyrophosphate coatings on chews, to prevent tartar and cavities are preferably from 0.4 to 0.5 weight percent (based on the total composition) of pyrophosphate. The recitation of a phosphate component at least about 0.05% is simply optimization of a result effective variable within a range that was previously taught by the prior art.

With regard to instant claim 47, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have included at least about 0.5% of phosphate by weight of the composition because Axelrod teaches inclusion of minerals to meet the comprehensive needs of the animal and ensure proper

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health and Spanier teaches that pyrophosphate coatings on chews, to prevent tartar and cavities are preferably from 0.4 to 0.5 weight percent (based on the total composition) of pyrophosphate. The recitation of a phosphate component at least about 0.5% is simply optimization of a result effective variable within a range that was previously taught by the prior art.

Applicant alleges that combination of Axelrod, Spanier, Koller, Merck, Lacombe, and Knapp fail to provide one of ordinary skill with a reasonable expectation of success in arriving at the current claims (Reply, page 24, paragraph two). The examiner disagrees. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Furthermore, with regard to the subject matter of the selected references, M.P.E.P. § 2123 discloses, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). Lastly, with regard to Applicant's allegation that one of ordinary skill in the art would have no reasonable expectation of success in combining the references to arrive at the claimed invention,

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M.P.E.P. § 2143 states, "Obviousness does not require absolute predictability of success." *Id.* at 903, 7 USPQ2d at 1681.

Instant claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication No. 2002/0119224 (hereinafter '224) by Axelrod, and U.S. Patent No. 5,011,679 (hereinafter the '679) by Spanier *et al.*

Axelrod teaches an animal chew toy (paragraph 1). One of objectives of the chew toy is to enrich the animal's diet with vitamins/minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6). Axelrod teaches the limitations of instant claim 48 by teaching preferential inclusion of manganese, and copper in the composition and discloses potential inclusion of tin (paragraph 16). It is evident that these minerals are in a soluble form, since it is taught that "the additives are incorporated into a soaking solution and allowed to coat and or penetrated the molded chew toy. Preferably a water solution containing the vitamins/minerals and/or herbs can be employed (paragraph 18). Axelrod also recognizes a need for inclusion of vitamin and mineral supplements (such as glucosamine) to ensure proper health and prevent malnutrition (paragraph 4). Axelrod teaches that phosphorus is present (paragraph 16).

Axelrod does not teach inclusion of a phosphate on the surface of the chew as set forth by instant claim 48.

Spanier teaches the limitations of instant claim 48 by teaching a rawhide chew containing a pyrophosphate coating (Abstract). The object of the chew is to prevent

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tartar accumulation on dog's teeth by the chewing and eating of raw hide having a coating containing pyrophosphate (Col. 8, lines 1-5). Spanier teaches that the inorganic pyrophosphates used in the invention are anti-tartar, anti-plaque or anticalculus agents (column 9, lines 55-60) and have an anti-cariogenic effect (Col.8, lines 34-41). It is preferred that the pyrophosphates are water soluble (Col. 11, lines 37-38). Spanier recognizes that tartar is detrimental to animal health by teaching that calculus deposits (tartar) are constant sources of irritation of the gingiva and thereby and thereby are a contributing factor to gingivitis and other diseases of the supporting structures of the teeth, irritation decreasing the resistance of tissues to endogenous and exogenous organisms (column 1, lines 20-35). Spanier teaches that the coating slurry (which contains the pyrophosphate) may be applied to the rawhide chew by any suitable means such as spraying or soaking (Col. 14, lines 1-3).

Therefore, it would be *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made, to include a water-soluble pyrophosphate in the soaking solution taught by Axelrod to coat and penetrate Axelrod's animal chew toy in order to improve the chew. One would have been motivated to do so because Axelrod recognizes a need for inclusion of vitamin and mineral supplements to provide for the comprehensive and proper nutritional needs of the animal and Spanier teaches that pyrophosphate coatings on chews prevent tartar and cavities.

Applicant alleges that combination of Axelrod and Spanier fail to provide one of ordinary skill with a reasonable expectation of success in arriving at the current claims

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(Reply, page 24, last paragraph; page 25, first paragraph). The examiner disagrees. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Furthermore, with regard to the subject matter of the selected references, M.P.E.P. § 2123 discloses, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). Lastly, with regard to Applicant's allegation that one of ordinary skill in the art would have no reasonable expectation of success in combining the references to arrive at the claimed invention, M.P.E.P. § 2143 states, "Obviousness does not require absolute predictability of success." *Id.* at 903, 7 USPQ2d at 1681.

Instant claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Axelrod and Spanier, as applied to instant claim 48 above, in further view of U.S. Patent No. 6,060,100 (hereinafter '100) by Koller.

Axelrod teaches the limitations of instant claim 49 by teaching that collagen may be present with *either* casein, starch, vegetable matter, rawhide, peanut bits/flour, animal meal and/or any other thermoplastic resin (paragraph 8; italics by examiner for

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emphasis). Axelrod teaches inclusion of rawhide in a chew (paragraph 29) and chews that are rawhide-free (paragraph 28). Axelrod also recognizes a need for inclusion of vitamin and mineral supplements (such as glucosamine) to provide for animal's comprehensive and proper nutritional needs are maintained.

Axelrod does not provide a rationale as to why one chew (rawhide-containing versus rawhide-free) would be preferable over the other, as set forth by instant claim 49.

Koller teaches that "rawhide is particularly bad for a dog's health as it is not digestible" (Col.1, lines 37-38).

Therefore, it would be *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made make Axelrod's chew rawhide-free as taught by Axelrod. One would have been motivated to do so because the Axelrod expresses a desire to ensure the proper health of an animal and Koller teaches that rawhide is bad for a dog's health.

Applicant alleges that combination of Axelrod, Spanier, and Koller fail to provide one of ordinary skill with a reasonable expectation of success in arriving at the current claims (Reply, page 25, last paragraph; page 26, first paragraph). The examiner disagrees. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Furthermore, with regard to the subject matter of the selected references,

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M.P.E.P. § 2123 discloses, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). Lastly, with regard to Applicant's allegation that one of ordinary skill in the art would have no reasonable expectation of success in combining the references to arrive at the claimed invention, M.P.E.P. § 2143 states, "Obviousness does not require absolute predictability of success." *Id.* at 903, 7 USPQ2d at 1681.

Instant claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Axelrod, Spanier *et al* and Koller, as applied to instant claims 48 and 49 above, in further view of *The Merck Veterinary Manual 8th Edition* as copyrighted in 1998.

The limitations of instant claims 48 and 49 are addressed above.

Axelrod specifically prefers inclusion of manganese, and copper in the composition and discloses potential inclusion of tin (paragraph 16). Axelrod also teaches that one of its objectives is to enrich the animal's diet with vitamins/minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6). The '244 prior art also teaches that one of the deficiencies of natural, organic, and vegetarian diets developed by owners is that many of the published recipes have not been properly balanced using nutrient averages as taught by *The Merck Veterinary Manual 8th Edition* (paragraph 4).

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Axelrod does not teach an edible composition comprising at least about 0.01% mineral component as set forth by instant claim 50.

The Merck Veterinary Manual 8th Edition teaches the limitations of instant claim 50 by teaching the American Association of Feed Control (AAFCO) Nutrient Requirements for dogs. In particular, the minimum amount of manganese required in dog food is 5 mg/kg, (or 0.0005% by weight), with no upper limit taught. The minimum amount copper required in dog food is 7.3 mg/kg, (or 0.00073% by weight) while the maximum amount of copper permitted is 250 mg/kg (0.025% by weight; page 1626) . Therefore the amount of the minerals can range from 0.00123-0.0255% (page 1626), which is at least about 0.01%

Therefore, it would have been *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made to optimize the amount of minerals in the chew taught by Axelrod. One would have been motivated to do so because Axelrod teaches enriching the chew with vitamins, minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6). One would have been further motivated to supply a mineral component at least 0.01% of the composition because the *Merck Veterinary Manual 8th Edition* teaches a range of amounts that are acceptable to meet a dog's nutrient requirements for copper and manganese. The range for these two metals falls within the claim limitations, "of at least about 0.01%." Furthermore, recitation of a mineral component, "of at least about 0.01%" is simply optimization of a result effective variable within a range that was previously taught by the prior art.

Applicant alleges that combination of Axelrod, Spanier, Koller, and Merck fail to provide one of ordinary skill with a reasonable expectation of success in arriving at the current claims (Reply, page 26, last paragraph). The examiner disagrees. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Furthermore, with regard to the subject matter of the selected references, M.P.E.P. § 2123 discloses, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). Lastly, with regard to Applicant's allegation that one of ordinary skill in the art would have no reasonable expectation of success in combining the references to arrive at the claimed invention, M.P.E.P. § 2143 states, "Obviousness does not require absolute predictability of success." *Id.* at 903, 7 USPQ2d at 1681.

Instant claims 51-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Axelrod, Spanier *et al*, Koller, and *The Merck Veterinary Manual 8th Edition* as

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copyrighted in 1998, as applied to instant claims 48-50 above, in further view of U.S.

Patent No. 6,277,435 (hereinafter '435) by Lacombe *et al.*

The limitations of instant claims 48-50 are addressed supra.

Axelrod teaches the limitations of instant claim 51 by teaching preferential inclusion of manganese, and copper in the composition and disclosing potential inclusion of tin (paragraph 16). Axelrod also teaches that one of its objectives is to enrich the animal's diet with vitamins/minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6). Axelrod teaches that the minerals are incorporated in a soaking solution and that the minerals can penetrate the chew (paragraph 18), demonstrating that these are water-soluble mineral salts.

Axelrod does not disclose specific water soluble mineral salts as set forth by instant claim 51.

Axelrod does not teach that the edible composition comprises a polyphosphate, as set forth by instant claim 52.

Axelrod does not teach that the edible composition comprises a pyrophosphate, as set forth by instant claim 53.

Axelrod does not teach that the edible composition comprises about 0.5% of the pyrophosphate component and at least 0.02% of the mineral component as set forth by instant claim 54.

Lacombe teaches the limitations of instant claim 51 by teaching a pet food which can be served daily, with noticeable improvement in the animal's health" (Col.3, lines 1-

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3). This pet food contains the soluble mineral components copper sulfate, and manganese sulfate (Col.4, lines 3-10).

Spanier teaches the limitations of instant claims 52, 53 and 54 by teaching a rawhide chew containing a pyrophosphate coating (Abstract). Spanier teaches that the pyrophosphates are used in a sufficient amount to deliver (preferably) from 0.4 to 0.5 weight percent (based on the total composition) of pyrophosphate (Col. 12, lines 40-45) (which is at least about 0.02% of the composition) to provide an anti-cariogenic effect (Col.8, lines 34-41).

The Merck Veterinary Manual 8th Edition (Merck) teaches the limitations of instant claim 54 by teaching that the minimum nutrient requirement for dogs for zinc, manganese, and copper (all of which are included in the composition taught by Axelrod) is 0.012%, 0.0005%, and 0.00073% respectively by weight (page 1626). The sum of these percentages is 0.013%, which is at least about 0.01% and teaches the limitations of instant claim 39. With regard to instant claim 42, Merck teaches that the minimum amount of manganese required in dog food is 5 mg/kg, (or 0.0005% by weight). The minimum amount copper required in dog food is 7.3 mg/kg, (or 0.00073% by weight) while the maximum amount of copper permitted is 250 mg/kg (0.025% by weight). The minimum amount of zinc required is 0.012%. The maximum amount of zinc required is 0.1 % (page 1626). Therefore the amount of the recited minerals can range from 0.01323-0.1255% (page 1626),

With regard to instant claim 51, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to include copper sulfate,

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manganese sulfate, in the chew taught by Axelrod. One would have been motivated to do so because Axelrod expresses a desire to enrich the chew with vitamins, minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6). Manganese and copper are taught to be included among minerals to be included in the chew of the Axelrod and may be added to the soaking solution. Copper sulfate and manganese sulfate are water soluble salts of these recited minerals and are taught to be to be edible and desirable in pet foods by Lacombe.

With regard to instant claim 52, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to improve the Axelrod's chew toy by adding pyrophosphate salts (i.e. a polyphosphate) to the chew toy because Axelrod recognizes a need for inclusion of vitamins, minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained to ensure proper health and Spanier teaches that inclusion of pyrophosphate (i.e. polyphosphate) salts in chews prevents tartar and reduces plaque both of which cause gingivitis and constant irritation to the gums and other problems.

With regard to instant claim 53, would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to improve the Axelrod's chew toy by adding pyrophosphate salts to the chew toy because Axelrod recognizes a need for inclusion of minerals to ensure that the animal's comprehensive and proper nutritional needs are maintained to ensure proper health and Spanier teaches that inclusion of pyrophosphate salts in chews prevents tartar and reduces plaque both of which cause gingivitis and constant irritation to the gums and other problems.

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With regard to the limitations of instant claim 54, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have added at least 0.05% of a phosphate component to Axelrod's chew toy because Axelrod recognizes a need for inclusion of minerals to ensure that the animal's comprehensive and proper nutritional needs are maintained to ensure proper health and Simone teaches that inclusion of pyrophosphate salts in an amount of 0.5 % to about 15% dry weight in chews prevents tartar and reduces plaque both of which cause poor oral health, periodontal disease, constant irritation and other problems. Recitation of a phosphate component, "at least about 0.05%" is simply optimization of a result effective variable within a range that was previously taught by the prior art. it would have been *prima facie* obvious to anyone of ordinary skill in the art at the time the invention was made to include at least about 0.02% minerals in the composition taught by Axelrod because Axelrod teaches enriching the chew with vitamins, minerals and herbs to ensure that the animal's comprehensive and proper nutritional needs are maintained (paragraph 6) and the proper amount of zinc, manganese, and copper required to meet the nutrient requirement for a dog ranges from 0.01323-0.1255%. The recitation of a mineral component greater than 0.02% is simply optimization of a result effective variable within a range that was previously taught by the prior art.

Applicant alleges that combination of Axelrod, Spanier, Koller, Merck and Lacombe fail to provide one of ordinary skill with a reasonable expectation of success in arriving at the current claims (Reply, page 27, first paragraph). The examiner disagrees.

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In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Furthermore, with regard to the subject matter of the selected references, M.P.E.P. § 2123 discloses, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned.

They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). Lastly, with regard to Applicant's allegation that one of ordinary skill in the art would have no reasonable expectation of success in combining the references to arrive at the claimed invention, M.P.E.P. § 2143 states, "Obviousness does not require absolute predictability of success." *Id.* at 903, 7 USPQ2d at 1681.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LORI MATTISON whose telephone number is (571)270-5866. The examiner can normally be reached on 8am-6pm (Monday-Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. M./

Examiner, Art Unit 1619

/MP WOODWARD/

Supervisory Patent Examiner, Art Unit 1615